K002362

NOV - 1 2000

510(k) Summary

Sponsor	Synthes (USA) 1690 Russell Road Paoli, PA 19301 Bonnie Smith (610) 647-9700
Device Name	Synthes (USA) Calcium Sulfate Bone Void Filler Pellets
Classification	Unclassified. The Device Product Code is 87 MQV.
Predicate Device	Wright Medical Technology's OsteoSet® Pellets
Device Description	Synthes Calcium Sulfate Pellets are composed of a porous, osteoconductive, bone void filler material consisting of calcium sulfate dihydrate and stearic acid. When used according to directions, the biodegradable, radiopaque pellets are resorbed in approximately 30 - 60 days and replaced by natural bone. The cylindrical pellets weigh approximately 100 mg and are supplied in capped, glass vials in sizes of 50, 100 and 200 pellets per vial. The product is pre-sterilized by gamma radiation and is not intended to be resterilized. It is for single use only. Synthes Calcium Sulfate Pellets have the same dissolution rate, compression strength and mass to volume ratio characteristics as the predicate device.
Intended Use	Synthes Calcium Sulfate Pellets are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The pellets are to be gently packed into bony voids or gaps of the skeletal system including the extremities, spine, and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The pellets provide a bone void filler that resorbs and is replaced with bone during the healing process. Because the pellets are biodegradable and biocompatible, they may be used at an infected site.
Material	Calcium Sulfate

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2000

Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
Post Office Box 1766
Paoli, PA 19301

Re: K002362
Synthes Calcium Sulfate Pellets
Regulatory Class: unclassified
Product Code: MQV
Dated: August 2, 2000
Received: August 3, 2000

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use Statement

510(k) Number (if known): K002362

Device Name: Synthes (USA) Calcium Sulfate Bone Void Filler Pellets

Indications:

Synthes Calcium Sulfate Pellets are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The Pellets are to be gently packed into bony voids or gaps of the skeletal system including the extremities, spine, and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The Pellets provide a bone void filler that resorbs and is replaced with bone during the healing process. Because the Pellets are biodegradable and biocompatible, they may be used at an infected site.

Contraindications:

This product is not intended to provide structural support during the healing process; therefore, Synthes Pellets are contraindicated in cases where structural support of the skeletal system is required.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002362